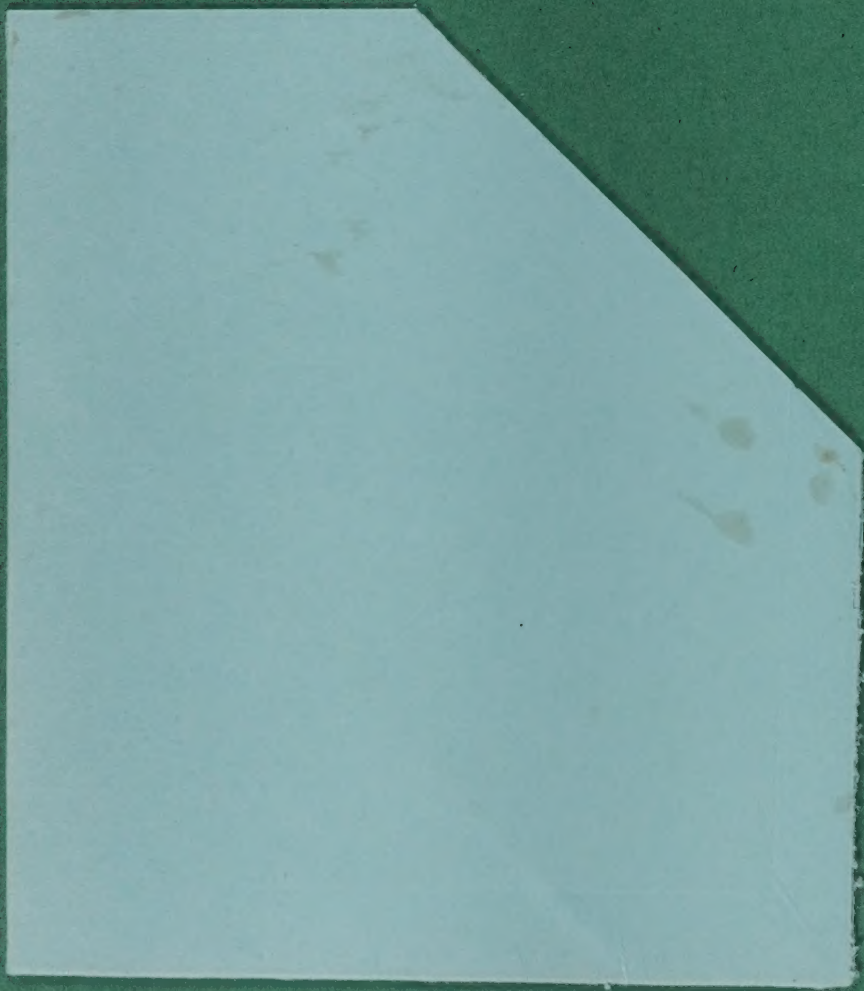


NATIONAL IMMUNIZATION PROGRAMME

**MANAGE THE
COLD CHAIN SYSTEM**



**Ministry of Health and Family Welfare
Government of India
New Delhi
1989**



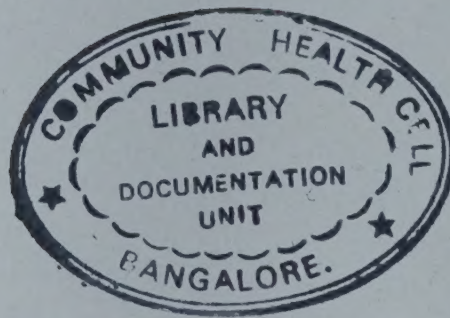
MANAGE THE COLD CHAIN SYSTEM

**Based on the WHO module for mid-level managers
— Manage the Cold Chain System**

02552

CH 131

N89



MANAGE THE COLD CHAIN SYSTEM

INDEX

	PAGE
Cold box	20
Cold Chain System	3
Cold room (WIC)	29
Control Vaccine Stocks	7, 24, 31
Checklist for Refrigerators	33
Day Carrier	9
Defrosting of Refrigerator	21
Dial Thermometer	21
Diluent	24
Distribution of Vaccines	24, 31
Estimates of Vaccine Requirements	5, 14, 26
Freezer	30
Ice Packs	9, 24, 30
ILR	20
Potency Test	34
Refrigerators	18
Storage of Vaccines	1, 4, 14, 17, 24, 29
Storage temperature	22, 33
Thermocole Box	9
Vaccine Administration	10
Vaccine Carriers	7

MANAGE THE COLD CHAIN SYSTEM

INTRODUCTION

Vaccination activity should not be an end in itself. Vaccinations should lead to immunity against a particular disease and reduction in morbidity and mortality.

Providing vaccination does not guarantee a reduction in disease morbidity and mortality. The FULL COURSE of the vaccines must be given at the RIGHT AGE and the vaccines must be POTENT. The system of keeping the vaccine potent is discussed in this module on Manage the Cold Chain System.

The cold chain is a system of transporting and storing vaccine at recommended temperatures from the manufacturer to the point of use. The cold chain system is necessary because vaccines are sensitive to heat. If they are exposed to heat, they will have a shorter life. Some vaccines are more sensitive to heat than others. Polio vaccine is the most sensitive to heat, while Tetanus vaccine is the least sensitive to heat.

Polio

DPT

Measles

BCG

DT

Tetanus

When vaccines lose their potency, they can no longer protect individuals from disease. Vaccine that has lost its potency is *useless*.

Vaccine potency cannot be regained once it is lost. Returning vaccine to the refrigerator or freezer will not restore its potency.

If vaccines are, however, kept at the recommended minimum temperatures, they will remain potent for a long period of time. All vaccines retain their potency at temperature between +2 to +8 degree C. The vaccines must be transported and stored at these temperatures at district and PHC stores.

For long term storage, measles and polio vaccines are kept at sub-zero temperatures. If freezers are available, these vaccines should be kept in a freezer.

DPT, DT, TT and B C G vaccines *should not be frozen*.

Vaccines should not be exposed to direct sunlight.

The loss of potency depends both on the temperature as well as the duration of exposure. The higher the temperature the shorter is the duration during which the vaccines become ineffective. For example, freeze dried measles vaccines kept at +5 degree C. will maintain its potency for at least two years. But the same measles vaccine exposed to +40 degrees C. will lose its potency in less than one day.

The essential elements of the cold chain are:

- people to organize and manage the vaccine's distribution
- equipment to store and transport vaccine;
- transport facilities.

Often the cold chain is thought to refer only to the refrigeration of vaccine. EVEN IF THE FINEST AND THE MOST MODERN EQUIPMENT AND TRANSPORTATION ARE AVAILABLE, THE COLD CHAIN WILL NOT BE EFFECTIVE UNLESS PEOPLE DO NOT HANDLE THE VACCINE PROPERLY. Therefore the importance of people in the cold chain needs to be stressed.

To manage the cold chain system, you must be sure that the following activities are adequately performed throughout the length of the cold chain:

- enumerate eligibles
- obtain vaccines
- maintain equipment
- maintain vaccines
- monitor cold chain

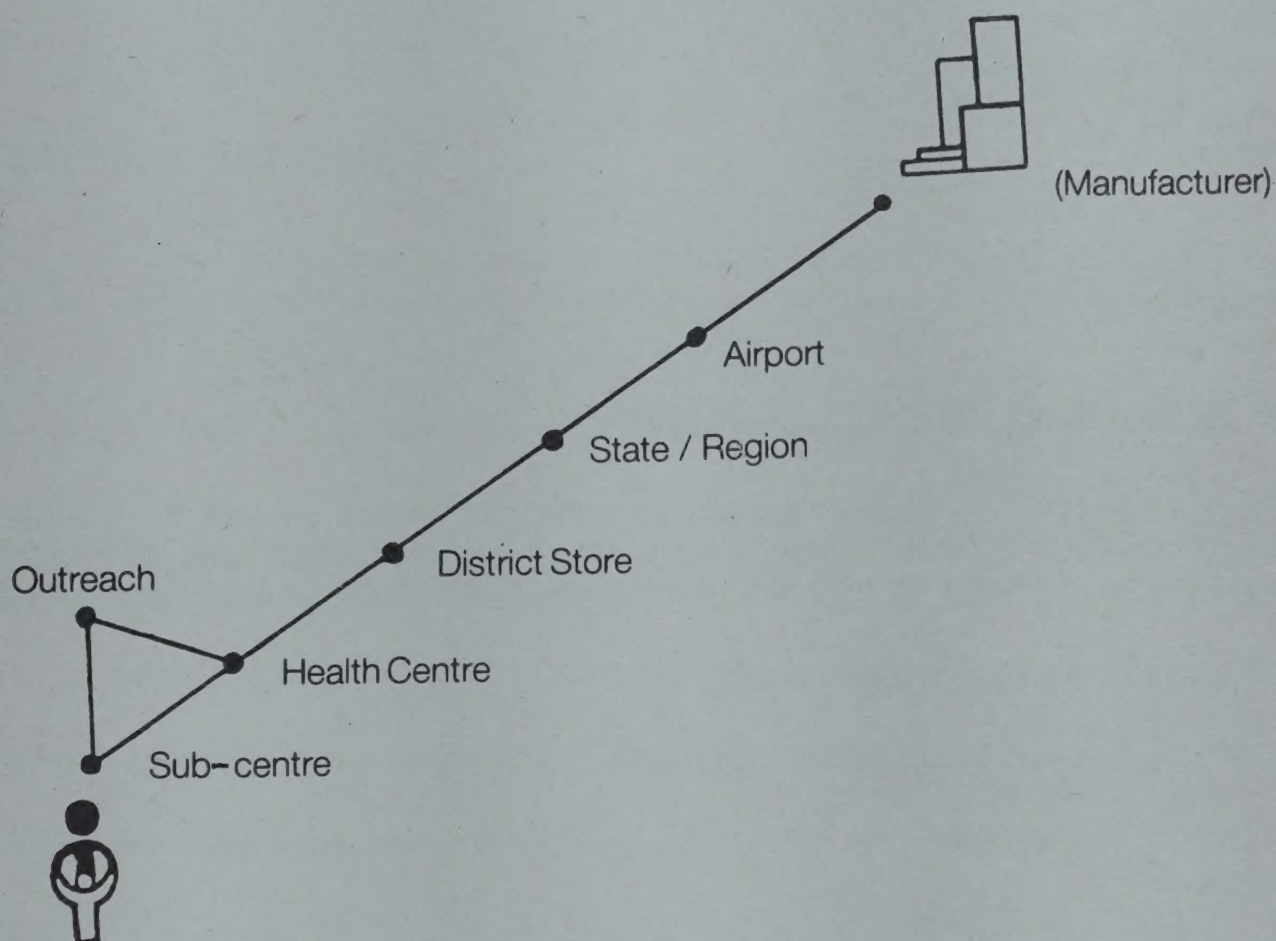
The specific tasks involved in these activities will vary according to the point along the cold chain at which they are performed.

STATEMENT OF PURPOSE

In this module you will practice skills which will assist you in performing important activities in the cold chain system for which you are responsible.

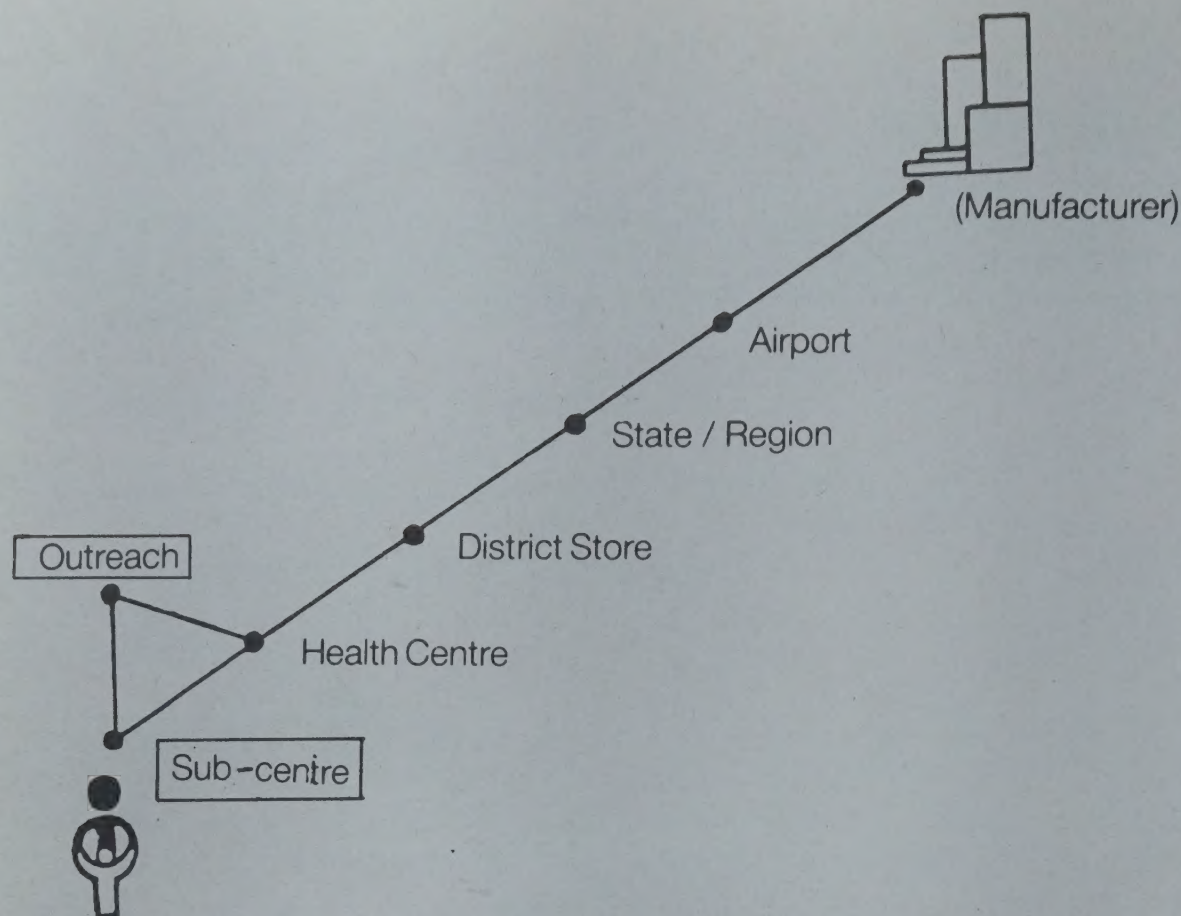
COLD CHAIN SYSTEM

The cold chain consists of a series of transportation links during which adequate refrigeration is required to maintain vaccine potency. The risk of cold chain failure increases as the vaccine moves along the cold chain from the manufacturer to the mother or child receiving it.



This module describes in detail the most important activities to be performed at the following links in the cold chain:

- 1.0 sub-centre /village
- 2.0 primary health centre
- 3.0 district store



1.0 SUB-CENTRE/VILLAGE LEVEL

The risk of cold chain failure is greatest at sub-centre and village level. For this reason, the vaccinator is the most important link in the cold chain. **VACCINES ARE NOT STORED AT THE SUB-CENTRE LEVEL AND MUST BE SUPPLIED ON THE DAY OF USE.**

In order to keep vaccines safe at this level,

- only the required quantities must be supplied;
- the vaccine carrier must have frozen ice-packs or the thermocol carrier, should be well packed with ice;
- vaccinations must be given in the shade and the vaccines must be kept on an ice-pack or in a cup of ice. Only one vial of each vaccine is taken out at a time.
- unused vials must be returned to the PHC the same day.
- opened vials should also be returned at the end of the session to the P H C for discarding.
- Details of used and returned vials should be maintained in the vaccine monitoring sheet (Anexure-1)

You will assign the responsibility of vaccine supplies to the supervisors at the PHC. But the final responsibility for ensuring that the cold chain operates efficiently and effectively is yours. You must make sure that your supervisors and the staff at the PHC and the sub-centre know how to calculate vaccine requirements and look after the vaccine carriers and other cold chain equipments.

1.1 ENUMERATE ELIGIBLES:

The vaccine requirements depend on the eligibles and the number of sessions to be held. The simplest and best way to know the eligibles is HOUSE TO HOUSE ENUMERATION OF PREGNANT WOMEN AND INFANTS. The village-wise enumeration at a particular period should get the information of infants according to month of birth. Though enumeration can be done at any time in the year, it is ideal to do in the first week of April every year. Thereafter regular updating of the eligibles must be done during the routine visits. However, the number of eligibles in the future months can be assumed to be the same as the corresponding period of the previous year. Pregnant women should be registered at the earliest period of pregnancy & expected date of delivery (E.D.D.) should be worked out. Enumeration to be done as per the proforma (annexure-2, 3)

1.2 OBTAIN VACCINES

Estimation of the vaccine requirements and ordering for the right quantities of vaccines is critical for maintaining the cold chain. The requirements depend on the population to be covered and the number of sessions to be held (periodicity of supply). Estimation based on the following formula will enable the supervisors to assess the vaccine requirements and to verify the correctness of enumeration.

Estimates of vaccine requirements:

Total number of pregnant women/infants in the area

X Proposed coverage

X Number of doses of the vaccine to be given (including booster dose)

÷ vaccine administration rate * (V.A.R.)

÷ periodicity of supply (depending on the number of sessions held per month.)

FOR EXAMPLE, in an area with a population of 5,000, birth rate of 30/1000 and IMR or 100/1000 live births, the estimated number of pregnant women and infants is calculated as follows:

Eligibles

Pregnant women	= Population × BR
Infants	= Population × BR × (1 – IMR)
Pregnant women	= 5,000 × 0.03 = 150
Infants	= 5, 000 × 0. 03 × (1– 0.0) = 150 × .9 = 135

*Vaccine administration rate: It is the number of doses actually administered to beneficiaries out of one hundred doses of the vaccine.

Vaccine requirements are calculated based on the following formula: Number of vials required = Number of eligibles × expected coverage Number of doses ÷ V.A.R. ÷ Number of doses per vial

Instead of dividing by V.A.R., you can multiply by wastage Multiplication factor (WMF) as indicated by equivalents below:

V.A.R.	W.M.F.
50%	2
75%	1.33
90%	1.11

Thus the formula using W.M.F. will be:

No. of eligibles × expected coverage × No. of doses × W.M.F. ÷ No. of doses per vial.

continuing with the example on previous page,

$$\text{Requirement of T.T.} = 150 \times \frac{100}{100} \times 2 \times 1.33 = 400 \text{ doses.}$$

This is annual requirement of T.T. for pregnant women. Monthly requirement = $400 \div 12 = 34 \text{ doses} \div 10 = 4 \text{ vials}$. If sessions are held fortnightly, divide by 24 & if weekly, divide by 52.

Although minimum coverage required for DPT, OPV, B C G & Measles is 85%, it is better to calculate vaccine requirements for 100%. Accordingly in the example cited, requirement of DPT/OPV will be:

$$135 \times \frac{100}{100} \times 4 \times 1.33 = 720 \text{ doses (4 doses include 3 primary and one booster)}$$

Accordingly, monthly & fortnightly requirements will be 60 and 30 doses.

$$\text{B C G/Measles} = 135 \times \frac{100}{100} \times 1 \times 2 = 270 \text{ doses}$$

Accordingly, monthly & fortnightly requirements will be 25 and 13 doses.

The vaccines are supplied in 10 or 20 dose vials or ampoules. The required number of doses are divided by 10 or 20 and rounded off to the next higher number of vials or ampoules.

Since the sub-centres are not supposed to keep vaccines there will be no balance stocks from previous supplies.

You must monitor the performance reports from the sub-centres to ensure that the expected number of pregnant women and infants are being immunized and the vaccines are not wasted. If the attendance is low, vaccine supplies must be suitably reduced till you can find out the reasons and take corrective measures to step up coverage.

The administration rate of the vaccines will depend on the number of sessions held and the attendance at the sessions. The fewer the number of pregnant women and infants per session the lower will be the administration rate. This is because opened vials must be discarded at the end of the session. On an average, the administrative rates of all vaccines is estimated to be 75% except BCG and measles -vaccines for which the administration rate is around 50%

Sometimes the services may have to be intensified to cover up the back logs. On the other hand, due to various reasons, such as heavy rains, priorities of other programmes, vacant posts etc. services may be considerably reduced during some months of the year. Thus, the monthly requirements will be more in some months and less in others. The supplies to the sub-centres must be adjusted accordingly with less vaccines being supplied over some months and more during the others. *This must be part of your planned activities.*

Before the vaccines are despatched, make sure to check the ice packs of the vaccine carriers. These should be frozen solid. If using thermocol carrier, these should be packed at least 1/3rd with ice.

Check that the types and amounts of vaccine and diluent are the same as you estimated.

Check that the expiry date on each vial of vaccine has not passed.

Check that DPT, DT, TT vaccines have not been frozen. The solution of such vaccines, on shaking, is not uniform. Small granules or floccules will be seen. Such vaccine also forms a sediment faster than the normal vaccine (shake test).

If you are sending vaccines to more than one sub-centre see that the sub-centres fall on the same route and if one person can deliver the vaccines taking the shortest route. The vaccines should reach the sub-centres in time for the vaccination sessions.

Any unused vaccine left at the end of the day should be returned to the PHC on the same day. No vaccine should be stored at the sub-centre. These vials should be kept in a separate box in the refrigerator marked "RETURNED". Put a rubber band around the vial to indicate that it was taken out once, two rubber bands if taken out twice. Any vial which has been taken out 3 times and not used, must be discarded. You must, however, be careful that this does not happen too often.

1.3 MAINTAIN EQUIPMENT

Vaccine and diluent taken from cold storage can be kept for several hours if packed properly in well-insulated cold chain containers. To do this, three types of cold chain containers are available for your use:

A cold box

vaccine carrier

A day carrier

These containers are designed to keep cold air inside and to prevent warm air from entering. So when you place vaccines inside a cold chain container, you are protecting them from the heat.

Ice packs are used to keep vaccines cool in a cold chain container. The checklists on the following pages describe how to use the containers and the ice packs.

At the sub-centre level vaccine carriers, day carriers are used. If these are not available you may use thermocole box with ice.

VACCINE CARRIERS are used for carrying small quantities of vaccines to the sub-centres or villages by insulation material, the quality and thickness of which determine the cold life of the carriers. The ice packs for lining the sides of the carrier should be fully frozen and the lid of the carrier should shut tightly. THE VIALS OF DPT, DT AND TT VACCINES SHOULD NOT BE IN DIRECT CONTACT WITH THE FROZEN ICE PACKS.

To pack:

- Place fully frozen ice packs in the carrier
- Put vaccine vials and ampoules in a polythene bag & close the bag with a rubber band.
- Stack vaccine and diluent in the carrier.
- Place some packing material between DPT vaccine and the ice to prevent them from touching the ice packs.
- Secure the lid tightly.

If more than one vaccine carrier is being carried, keep the whole range of the vaccines required for the day's use in each carrier so that only one carrier is opened at a time.

To Keep in good condition when not in use:

- Clean inside after each use.
- Check after each use that the inside is dry.
- Examine inside and outside surfaces after each use for cracks.
- Keep plastic carriers out of direct sunlight, as this will heat them and may cause the plastic to crack;
- Do not sit or place anything heavy on a vaccine carrier.

The vaccine carriers with four ice packs can keep the vaccines cold for 2 days if the **ice packs used are fully frozen** and the lid of the carrier is kept tightly shut.

Day carriers i.e., smaller vaccine carriers are also available in India. These have 2 ice packs, one each at the top and bottom. They can carry only a few vials at a time and can keep vaccines safe only for one working day (6-8 hours).

The steps for keeping a day carrier in good condition are the same as for the vaccine carrier.

THERMOCOLE BOXES are available in the country in a variety of shapes and sizes. They are lighter and cheaper than vaccine carriers but are not as durable and have a shorter cold life. Since ice packs are not available with the thermocole boxes, ice is used for cooling. This is packed in a plastic bag and placed on the bottom and the TOP of the vaccine vials, but not in direct contact.

REMEMBER

Do not leave vaccine carriers in sunlight

Do not leave the lid open

Do not drop or sit on them

Keep clean and dry

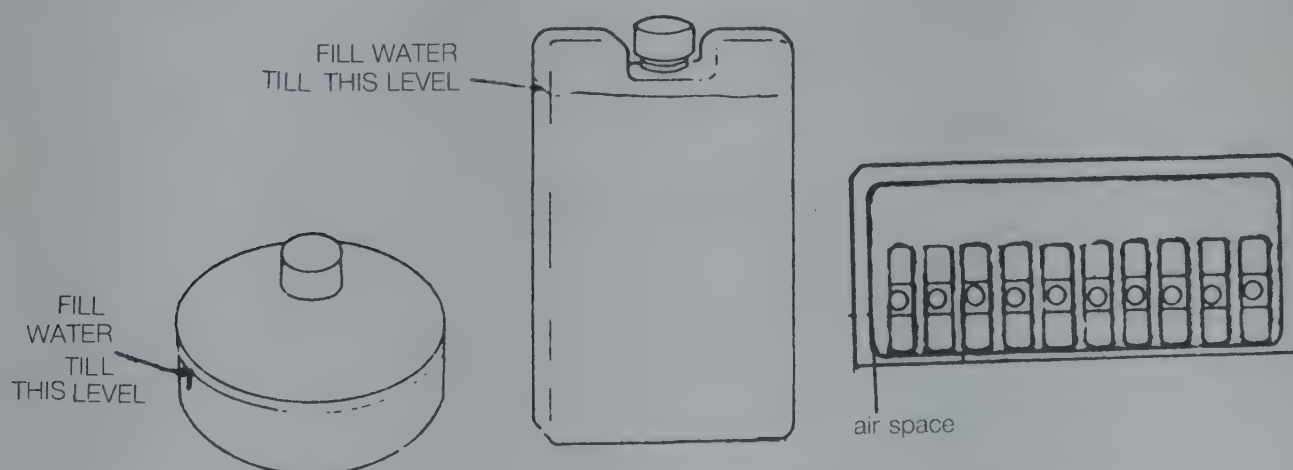
Use *frozen* ice packs

Use ice cubes in a polythene bag for a thermocole box

ICE PACKS

Ice packs are used for lining the walls of cold boxes and vaccine carriers to keep them cold. They are flat plastic bottles filled with water. The ice packs are prepared by keeping them in the freezer or in the freezer compartment of an ordinary refrigerator. The time taken to freeze an ice pack in the freezing compartment is reduced if the ice packs stand with their edges in contact with the evaporator and not flat on one another (see figure 1).

Salt should not be added to the water as it lowers the temperature to sub-zero temperature which is not recommended for DPT, DT, TT and B C G



You will need to prepare ice packs at the PHC for carrying vaccines to the sub-centres or the outreach sites. For full freezing of the ice packs, keep them in the freezing chamber of domestic refrigerator overnight (at least 12 hours).

1.4 MAINTAIN VACCINES

When administering vaccine to expectant mothers and infants at the vaccination site, *you must take great care not to expose the vaccine to heat and sunlight.* To do this:

- Select a vaccination site that is as cool as possible, preferably inside a room. If a room is not available, vaccinate in the shade. *Do not vaccinate in the sunlight.*
- Open the carrier only when necessary
- Remove vaccine and diluent from the vaccine container ONLY when you need it.
- Take only vial of one type of vaccine from the container at a time. Do not take the second vial from the carrier until it is needed.
- Secure the lid tightly after opening as soon as possible.
- Wrap the B C G ampoules in a foil or a dark paper to protect them from heat and light.
- When you take vaccine out of the container, place vials inside a cup containing ice. If the ice melts and no mothers and children are waiting, put the vials back into the cold chain container until a mother arrives. Then place the vials inside the cup with ice.
- When the vaccination session is completed, return all vials to the health centre store.

If ice packs in the carrier still contain ice, mark unopened vials by putting rubber band, and return them to the refrigerator. **BE SURE TO USE THESE MARKED VIALS DURING THE NEXT VACCINATION SESSION.**

Do not take the same vial of the vaccine out to the field more than three times. If a vial of vaccine has been taken to the field third time, return it to the P.H.C. after marking 'Discard'. You must however be careful that vaccines are not wasted in this way too often.

— Keep opened vials in a plastic bag and return these to P.H.C. at the end of the session for discarding by an identified person.

— If the ice in the cold chain container is *completely melted for less than one day*:

i) Discard polio vaccine, so that no one else can use.

ii) Mark the remaining DPT, Tetanus Toxoid, measles and BCG vaccine, return it to the refrigerator, and use it during the next vaccination session.

— If the ice in the cold chain container is **COMPLETELY MELTED FOR MORE THAN ONE DAY** throw away all vaccines.

- Keep a record of the vaccine you administer.
- Keep record of the batch numbers and the expiry dates of the vaccines used.
- Keep a record of vaccines returned to P.H.C.

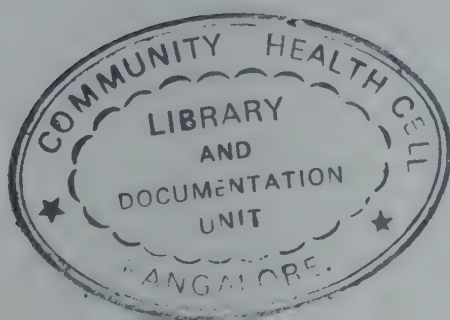
Exercise A

Instructions: Read the following situation and answer the questions below. Write your answers in the space provided after each question.

Situation: To months ago you administered measles vaccine to 37 children in Village "X" who were 9-12 months of age. Today you hear that in the past three weeks there have been 12 cases of measles and 2 deaths in Village "X" among these vaccinated children. This has been confirmed by an epidemiological investigation. Your supervisor has determined that the vaccine was potent when it was issued to you. But clearly, same vaccine was not potent when it was administered.

Questions: 1. What are five likely causes of this problem?

2. How would you try to prevent this problem from occurring again?



02552

211/31

12/09

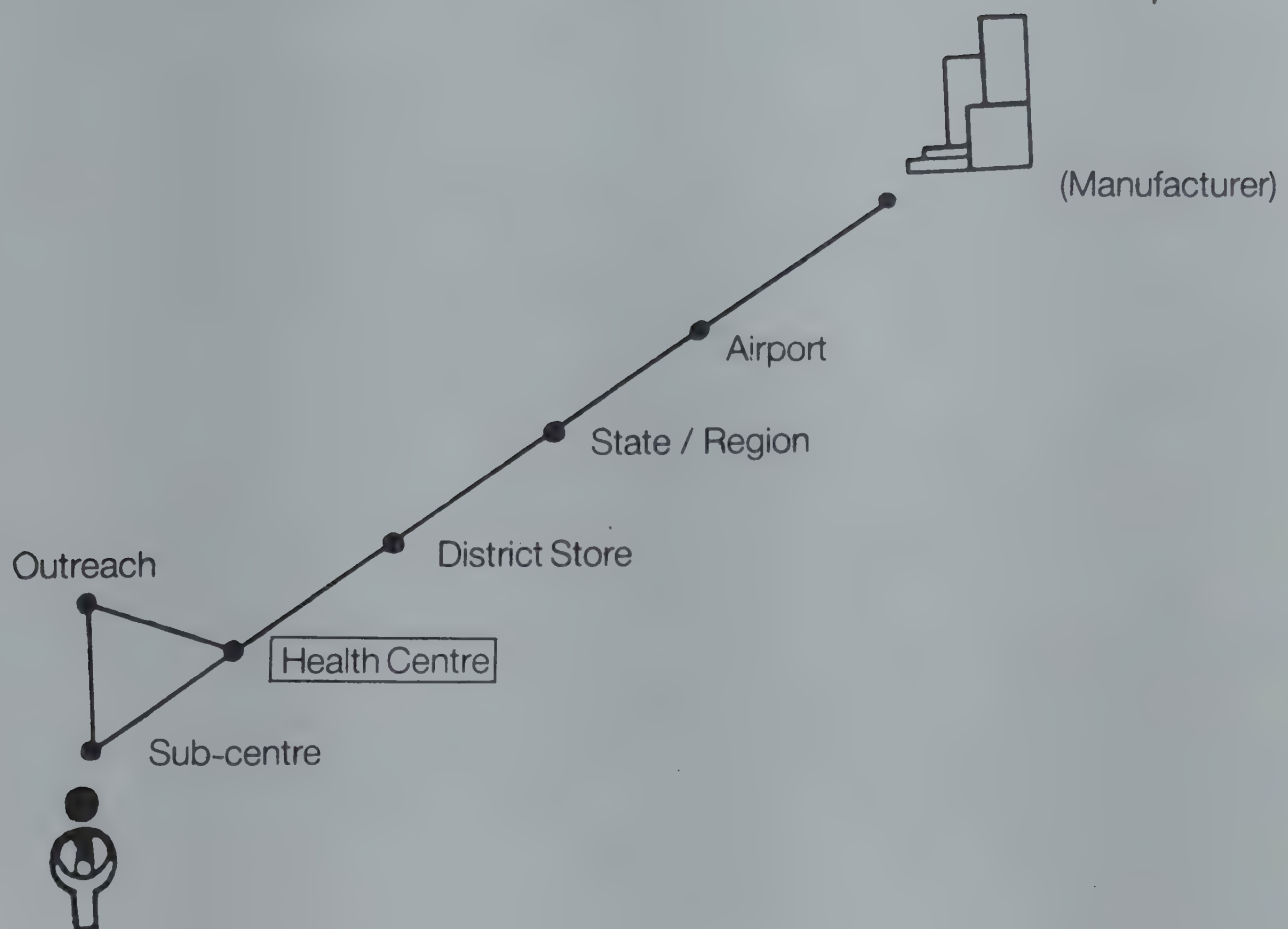
Exercise B

Instructions: Read the following situation and answer the questions below. Write your answers in the space provided after each question.

Situation: The frozen ice packs in your vaccine carrier melt within two hours.

Questions: 1. What are five likely causes of this problem?

2. How would you try to prevent this problem from occurring again.



2.0 PRIMARY HEALTH CENTRE

As a health centre manager, you have many responsibilities. One such responsibility is managing the cold chain. Although you may delegate some of your duties to others, the final responsibility for ensuring that the cold chain operates efficiently and effectively is yours. Your major duties are:

- 2.1 Obtain Vaccines.
- 2.2 Maintain equipment.
- 2.3 Maintain vaccines.
- 2.4 Distribute vaccines to the sub-centre and outreach sessions.
- 2.5 Monitor cold chain.
- 2.6 Train staff.

2.1 OBTAIN VACCINES

2.1.1 You will either collect vaccines from the district stores or these will be delivered to you. It is best that vaccines are obtained at regular intervals. For example, you might collect vaccines once a month or once every two weeks. However, you should not collect vaccines at intervals greater than once a month. This is because a PHC MUST NOT HOLD MORE THAN ONE MONTH'S STOCK. NO VACCINES SHOULD BE STORED AT THE SUB-CENTRES.

You must estimate your vaccine requirements well in time and inform the officer at the district level. This will enable him to place orders for the right quantities of the vaccines with the state officer. The manufacturer of the vaccines must know 9 months to one year in advance the quantities of vaccines he must produce. He will not be able to make available large quantities of vaccines at shorter notice.

It is important that you obtain the right amount of vaccine. If you obtain too little vaccine, you may cause delays in your immunization activities. If you obtain too much vaccine, some of it may expire or it may be kept longer than the recommended time. Remember, the longer you keep the vaccines at the PHC, the greater is the risk of a cold chain failure.

Estimates of vaccine requirements are done as given at Page 6. Always check your BALANCE STOCKS before placing fresh indents. Keep 10% additional vaccines as buffer stocks for any unforeseen demand. The stocks must be rotated so that no vaccine is kept for more than one month.

Exercise C

Instructions: Determine the number of doses of each vaccine you will actually need this year. You always need more vaccine than you plan to administer. This is because opened vials that still contain vaccine must be thrown away at the end of a vaccination session.

Situation: Your centre covers a population of 50,000. The birth rate is 30/1000 and infant mortality rate 90/1000. You plan to cover during this year 100% pregnant women and 85% infants. Vaccines are delivered to you once a month.

Exercise D

Instructions: Read the following situation. Then use the procedure described on page 5 to answer the questions below. Write your answers in the space provided after each question.

Situation: The number of children under 1 year of age in the area served by your health centre is 2,500. Your vaccination coverage target is 85% (or 0.85). You are currently halfway through a supply period of one month. The stock records show that you have a present stock of 1,500 doses of measles vaccine.

- Questions:*
1. Is there too much or too little measles vaccine in stock?
 2. What are the possible causes for this situation?
 3. What actions could be taken to correct it?
 4. How can the situation be prevented from occurring in the future?

2.1.2 When you go to the district store to collect your vaccine:

- Make sure you carry cold box or enough vaccine carriers to keep the vaccine you will collect.
- Check that the types and amount of vaccine and diluent are the same as you need.
- Check the expiry date on each vial of vaccine.
- Pack the vaccine and diluent into a cold box or the vaccine carriers quickly but properly.
- Take the vaccine and diluent to the health centre using the shortest route and cover the distance quickly but safely.
- Transfer vaccines to the refrigerator immediately after you arrive at the health centre.
- If your vaccine is delivered to you by the district store:
 - Confirm the arrival time through letter, telephone call or telegramme.
 - See if the vaccine was transported in a cold box or vaccine carrier with ice packs or ice.
 - Check that the types and amounts of vaccine and diluent are the same as you need.
 - Check the expiry date on each vial of vaccine.
 - Transfer vaccine to the refrigerator as quickly as you can.

2.2 MAINTAIN EQUIPMENT

If the cold chain is to be effective, its equipment must be properly maintained. The types of cold chain equipment found in most health centres are:

A refrigerator

A deep freezer

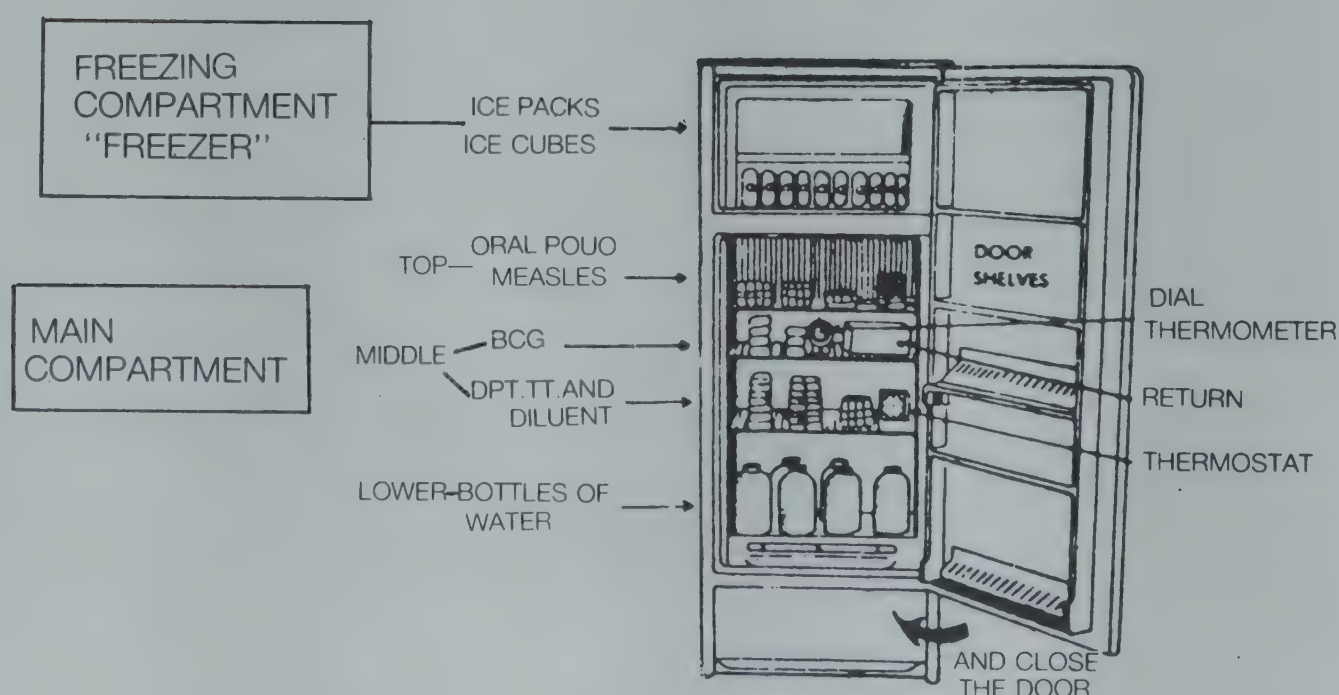
A cold box

A vaccine carrier

These equipments are designed to keep cold air inside and to prevent warm air from entering. So when you place vaccines inside these, you are protecting them from the heat.

REFRIGERATORS

your health centre should have at least one refrigerator. Most PHCs have also been supplied the top opening icelined refrigerators (ILRs). The refrigerators should be handled carefully so that the temperature in the cabinet does not rise above +8 degree C. If the refrigerator is opened frequently, it will not be able to maintain the required temperature. Many refrigerators get out of order soon after installation only because of poor maintenance.



The checklist given below will help to prolong the working life of the refrigerator and ensure the proper storage of the vaccines:

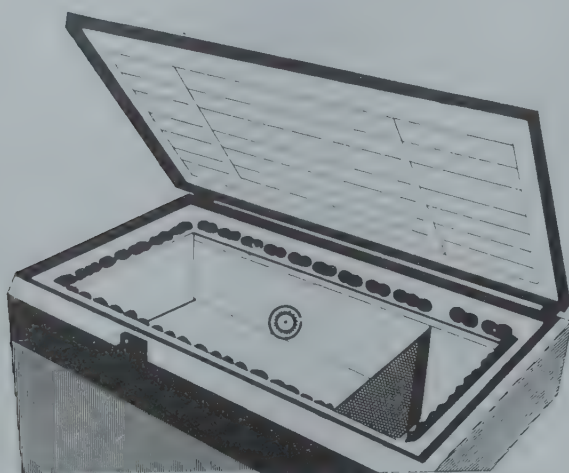
DOs

- keep the refrigerator in a cool room away from direct sunlight and at least 10 cms away from the wall.
- keep the refrigerator level.
- fix the plug permanently to the socket.
- use voltage stabilizer.
- keep the vaccines neatly with space between the stacks for circulation of air.
- keep the refrigerator locked and open it only when necessary.
- keep ice or ice-packs in the freezer and water bottles in the shelves not utilized for the storage of vaccines to keep the temperature down for a longer period in case of power failure.
- defrost periodically.
- check the temperature twice a day and maintain a record which should be supervised regularly.
- take remedial action if the temperature is not maintained within the prescribed limit.
- tape a sheet of paper outside the refrigerator which tells anyone finding the refrigerator not working:
 - whom to contact
 - where to check for a blown fuse
 - alternate place for vaccine storage.

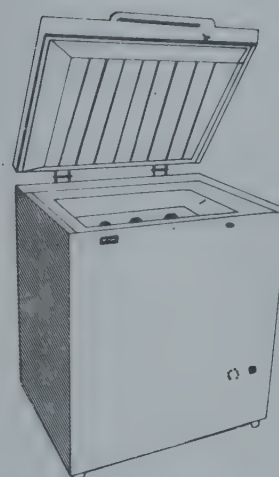
DON'Ts

- do not open the door unless necessary.
- do not keep vaccines in the door of the refrigerator.
- do not keep food or drinking water in the refrigerator.
- do not keep more than one month's requirements.
- do not keep "date expired" vaccines.

ICE-LINED REFRIGERATIONS (ILRs)



Icelined refrigerators (ILRs)



Vest Frost

ILRs are top opening refrigerators. Under the national immunization programme two types are in use-one with ice tubes (electrolux) and the other one with ice packs (vest frost) as the ice lining. These act as a buffer in case of power failure and the temperature inside the refrigerator does not rise.

The ILRs can, thus, with an electricity supply of even 8 hours in a 24 hour cycle keep the vaccines within the safe temperature range.

The bottom of these types of refrigerators is the coldest place. DPT and TT vaccines should not be kept directly on the floor of the refrigerators as they can freeze and get damaged. Keep DPT, DT and TT vaccines in the baskets provided with the refrigerator.

Keep a dial thermometer inside the ILR to record the daily temperature even if there is an in-built thermometer.

There is NO FREEZER COMPARTMENT in the ILRs. You cannot freeze ice packs or ice in the ILRs.

The electrolux type of ILR can be used as a deep freezer also by changing the switch to the appropriate position. There is no such arrangement in vestfrost ILR. There a deep freezer is supplied separately with this equipment. If you wish to prepare ice packs in these ILRs, you must switch it on to work as a freezer. But before you do this be sure that you have transferred DPT, DT, TT and other vaccines that are damaged at sub-zero temperature, to another refrigerator or to an already prepared cold box. The cold box must have the required number of solidly frozen ice packs.

Ordinary, ILRs must be used only as a refrigerator for storing vaccines even when there is another refrigerator in your office. The risk of cold chain failure is far less in an ILR than in a conventional refrigerator specially where there are periodic power failures.

DEEP FREEZER : It is also a top opening equipment. It is to be used for storing polio & measles vaccine and freezing of ice packs. A pair of a deep freezer and a vestfrost ILR is connected to a common voltage stabilizer.

DEFROSTING

The temperature in the refrigerator freezer can rise if there is a thick layer of ice around the freezer. It is therefore necessary to defrost the refrigerator periodically. This should be done if the ice in the freezer is more than 1 cm thick.

Most refrigerators now have automatic defrosting switch. When the button is pressed the cooling in the freezer compartment stops and the ice starts melting. Put back the flap of the tray beneath the freezer compartment to allow the water to escape to the tray under the refrigerator. After the ice has melted, the refrigerator will automatically start again. The vaccines need not be removed from the refrigerator. However, remove the ice packs / ice from the freezer compartment and keep them in the cabinet of the refrigerator. Do not open the door of the refrigerator during this period.

Do not forget to put the flap of the tray back after defrosting, otherwise the cold air will not flow down and the temperature in the cabinet will rise.

For defrosting the ILR conventional refrigerator without automatic defrost deep freezer you would need to remove the vaccines to a cold box or to another refrigerator and to switch off the equipment. The ice packs for the cold box should be prepared before defrosting the ILR so that the vaccines are not exposed to temperatures above +8 degree C. Use a clean cloth for cleaning and drying the inside of the equipment.

Do not use any sharp instruments for removing the ice as this can damage the equipment.

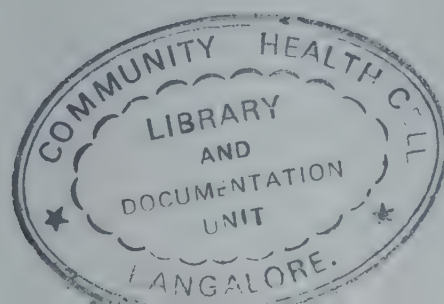
After defrosting, ensure that desired temperature has been attained in the equipment. Only then shift the vaccines to the equipment.

DIAL THERMOMETERS

Dial thermometers have been provided to record the temperature in the refrigerators. One dial thermometer should be kept in each refrigerator, including the ILRs. In the conventional refrigerators the dial thermometer should be kept in the top shelf. One person should be made responsible for recording the temperature. The booklet of 12 temperature recording forms should be kept on the top of the refrigerator and must be checked daily to see that the temperature is maintained.

TUBULAR ALCOHOL THERMOMETERS

These are being supplied with vestfrost equipment. They serve the same purpose as the dial thermometer.



02552

CH/31
149

RECORDING & MONITORING OF STORAGE TEMPERATURE

The temperature in the refrigerators **MUST BE MONITORED TWICE DAILY**. This is done in order to :

- record that vaccines were not exposed to temperature above +8 degree C.
- check that the equipment is working properly;

You must be careful to see that the temperature in the refrigerator does not rise above +8 degree C. You must check that the temperature does not fall below +2 degree C. as it damages the DPT group of vaccines. Adjust the thermostat switch in different seasons to maintain the inside temperature of the equipment well within the prescribed range.

COLD BOXES are big insulated boxes. They come in different sizes. Each one is supplied with requisite number of ice packs, usually twenty four.

Uses :

- Collect large quantities of vaccines.
- Transport large quantities of vaccine by vehicle to outreach sites.
- Store vaccines for upto five days, if necessary.

To pack :

- Place fully frozen ice packs side-by-side against the inside walls and floor of the cold box.
- Stack vaccine and diluent in the box.
- Place packing material between DPT vaccine and the ice pack to prevent vaccine from becoming frozen.
- Place ice packs over the top of the vaccine and diluent if there is room, so the vaccine
- Secure the lid tightly.

To keep in good condition when not in use :

- Clean and dry after each use.
- Examine inside and outside surfaces after each use for cracks.
- Check that the rubber seal around the lid is not broken; if so, replace it immediately.
- Adjust the tension on the latches so that the lid closes tightly.
- Oil hinges and locks routinely.

Exercise E

Instructions: Read the following situation and answer the question below. Write your answer in the space provided after the question.

Situation : The district store informs your health centre that it will not be able to deliver the vaccine you need on schedule.

Question : What would you do?

2.3 MAINTAIN VACCINES

2.3.1 STORE VACCINES PROPERLY

All vaccines removed from the refrigerator must be used or returned to the refrigerator after the vaccination session. Vaccine that has been returned to the refrigerator unused must be used during the following session, or failing this, during the third session. If it is not used during the third session, discard it.

To ensure that RETURNED vaccine is selected first, place these vials in a box in the refrigerator marked "returned". Put one rubber band for the first visit, and two if the vial was taken out twice.

The vaccine with the nearest expiry date could be used first. Vaccine that has been supplied earlier should be used first. Opened vials received for discarding can also be sent for potency testing.

If the vaccine date is expired, DO NOT USE IT.

Check that DPT, DT or TT vaccines have not been frozen. If these have been frozen, DO NOT USE THEM.

Diluent should be cooled before use. Keep the diluent in the lower shelves of the refrigerator. If the space is not adequate, the remaining stocks can be kept at room temperature. Sufficient quantity for the next day's use must be kept in the refrigerator and taken to the field in vaccine carriers. The diluent should not be frozen as the vials / ampoules are likely to crack.

Keep a record of storage temperature, monitor and take action when warranted.

2.4 DISTRIBUTE VACCINES

You will be responsible for distributing vaccines for use in the sub-centres and also by the outreach teams. Before sending vaccines, you must ensure :

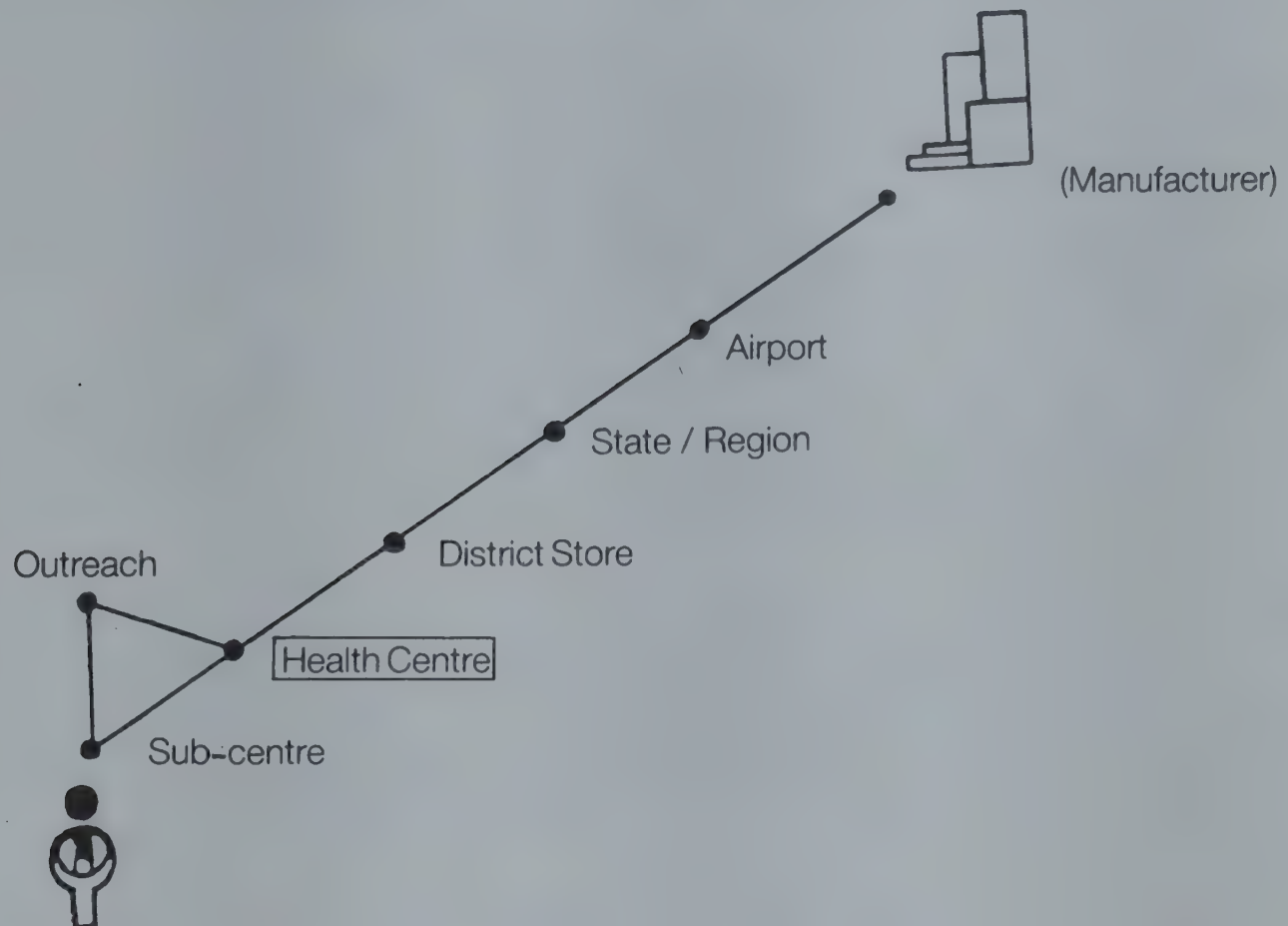
- actual requirements of the sub-centre / team;
- the ice packs of the vaccine carriers are frozen solid / there is adequate ice in the thermocol box.

The sub-centres should not be provided more than their daily requirement. No vaccine should be stored at the sub-centres. Unused vials of the vaccines should be returned to the PHC on the same day. If it is not possible to return the vaccines on the same day, they can be sent on the next day only if the ice packs / ice has not fully melted. Opened vials of the vaccines should be sent to PHC for discarding and not reused the next day.

In most PHCs, 3 or 4 sub-centres have immunization sessions on the same day. Plans for organizing these sessions should be carefully laid out keeping in mind the logistics of vaccine supplies. You will need to have enough vaccine carriers with ice packs and somebody to deliver them in time. You must also make arrangements for bringing back the unused vials.

If you are planning outreach sessions, you may need a large number of ice packs. You can only freeze a limited number in one day, even in a freezer. You must, therefore, start freezing ice packs several days in advance, adding more ice packs everyday.

If ice factories are located near your centre, take their help in freezing ice packs.



3.0 DISTRICT STORE

As a district manager, you have many responsibilities. One such responsibility is managing the cold chain. Although you may delegate some of your duties to others, the ultimate responsibility for ensuring that the cold chain operates efficiently and effectively is yours. Your primary duties are :

- 3.1 Obtain vaccines.
- 3.2 Maintain equipment.
- 3.3 Maintain vaccines.
- 3.4 Distribute vaccines.
- 3.5 Monitor cold chain.
- 3.6 Train staff.

3.1 OBTAIN VACCINES

You will need vaccines to distribute to health centres in your region and to outreach units that operate out of your store. You will request needed vaccine from the State store. The State store will usually then make arrangements to deliver the vaccine to you. It is best if you collect vaccines at regular intervals. For example, you might collect vaccine once a month or once every two months. However, you should *not* collect vaccine at intervals greater than once every three months. This is because it is recommended that vaccine be stored *no longer than three months in the district stores*.

It is important that you obtain the right amount of vaccine. If you obtain too *little* vaccine, you may cause delays in your immunization activities. If you obtain too *much* vaccine, some of it may expire or it may be kept longer than the recommended time.

REMEMBER the vaccines have a limited shelf life and lose their efficacy easily if not handled properly. Order only the amounts actually required. Do not allow large balance stocks to accumulate. Check transport and storage arrangements before placing an indent for vaccine. One person should be made responsible for indenting, receiving, storing and distributing vaccines.

3.1.1. The procedure to estimate the amount of vaccine you need to collect is the same as described in section 1, page 6, so it will not be repeated. The amount of vaccine involved is much greater at the district, of course. ALWAYS CHECK YOUR BALANCE STOCKS BEFORE PLACING ORDERS FOR FRESH SUPPLIES. Keep 10% additional vaccines as buffer stocks for any unforeseen demand. The stocks must be rotated so that no vaccine is kept for more than 3 months.

Exercise F

Instructions : Read the following situation. Then use the procedures described at page 5 to answer the question below. Write your answer in the space provided after the question.

Situation : You are planning universal immunization coverage in your district. The total population of your district is 20.0 lakhs. The birth rate is 35.0 / 1000 and IMR 100 / 1000 live births. You expect to cover 100% of the pregnant women with 2 doses of TT and 85% of the infants with 3 doses each of DPT and Polio vaccines. You also need to collect vaccines for booster dose of DPT and OPV. You also aim to immunize 85% of the infants with BCG and measles vaccines. You receive vaccines once in 3 months.

Questions: 1. How many doses of each vaccine you would require?

2. How many doses of each vaccine you would need every quarter?

Exercise G

Instructions : Read the following situation. Then use the procedure described on page 5 to answer the question below. Write your answer in the space provided after the question.

Situation : You are planning the measles vaccine needs of your region. The total infant population in your district is 30,000. The percent of coverage expected is 85% (or 0.85). Your supply period is three months. You will have 3300 doses of measles vaccine in stock when the new supply arrives.

Question : How many doses of measles vaccine will you need to collect during one supply period?

When you have completed this exercise, consult a course manager.

3.1.2 Before the vaccine is delivered to you by the State store :

- Confirm the arrival time through letter, telegram or telephone call.
- Ensure that you have adequate storage space.

When the vaccine is delivered :

- Determine if the vaccine was kept below +8 degree C. during transportation. If not, do not use the vaccine unless specifically instructed to do so by the state officer.
- Check that the types and amounts of vaccines and diluents are the same as you ordered.
- Check that the expiry date on each vial of vaccine has not passed.
- Transfer the vaccines to the refrigerator / walk-in-cooler (WIC) as quickly as you can.

When you go to the State or regional store to collect your vaccine :

- Make sure you have enough cold boxes/vaccine carriers to keep your vaccines.
- Check that the types and amounts of vaccines and diluents are the same as you needed.
- Check that the expiry date of vaccine has not passed.
- Pack the vaccine into the cold boxes/vaccine carriers quickly but properly.
- Take vaccine and diluent to the district store using the shortest route, and cover the distance quickly but safely.
- Transfer vaccines to refrigerators/WIC immediately after you arrive.

3.2 MAINTAIN EQUIPMENT

If the cold chain is to be effective, its equipment must be properly maintained. The types of cold chain equipment found in most district stores are:

- A refrigerator and freezer
- A cold box
- A vaccine carrier

The large districts have been provided with cold rooms (walk-in-coolers - WIC).

3.2.1 COLD ROOMS are used for the storage of large quantities of vaccines. There should be an assured source of constant electric supply and regular monitoring of the temperature. Cold rooms should have free access 24 hours a day and 7 days a week, so that in case of any breakdown or power failures the defect could either be rectified or the vaccines transferred to an alternate place for storage.

One person should be made responsible for the WIC.

In case of major defects you must inform the State Immunization officer and the Ministry of Health and Family Welfare immediately.

Keep a list of private cold stores in the district headquarters in case of serious breakdowns or other emergencies.

3.2.2 AT THE DISTRICT LEVEL 300 FREEZERS have been supplied for:

- preparation of ice packs
- preparation of ice
- storage of polio, measles vaccines.

DPT, DT, TT, and B C G vaccines should not be kept in deep freezers.

Keep the freezers locked. The description of cold boxes and vaccine carriers have been given in earlier sections of this module.

Only a limited number can be frozen in one day even in a freezer. You must make your plans in advance and start freezing ice packs several days before you need them. You may sometimes need a large number of ice packs. If an ice factory is located nearby, you may seek its help in freezing ice packs for you.

3.3 MAINTAIN VACCINES

The objective of good vaccine handling is to minimize:

- the period of time in which all vaccines are exposed to temperatures above +8 degree C and some below 0 degree C.
- the period of time in which any vaccine remains in cold chain stores without being used.

REMEMBER:

- Do not keep vaccines for more than 3 months at the district stores.
- Do not keep vaccines for more than 1 month at PHC.
- Do not store any vaccines at sub-centres.
- All vaccines are safe at temperatures between +2 to +8 degree C. for 4 months at least.
- Keep all vaccines at +2 to +8 degree C. If you have a freezer, polio and measles vaccines can be kept in them.
- DPT, DT and TT vaccines should not be frozen. DO NOT ALLOW THEM TO FREEZE.
- Transport vaccines in cold boxes or vaccine carriers.
- Check ice packs before packing vaccines.
- Travel by the shortest route.

Control vaccine stocks

You should know the amount of vaccine you have in storage, and be sure that the vaccine which has the earliest expiry date is used first. If two shipments of vaccine have the same expiry date, the one which has remained longest in the store should be used first.

Keep separate datewise records of vaccine receipts, distribution and balance sheet for each type of vaccine and each size of vial. Note the expiry date of incoming batches and mark the arriving vaccine with the arrival date (to provide a useful check on the age of the vaccine in the store).

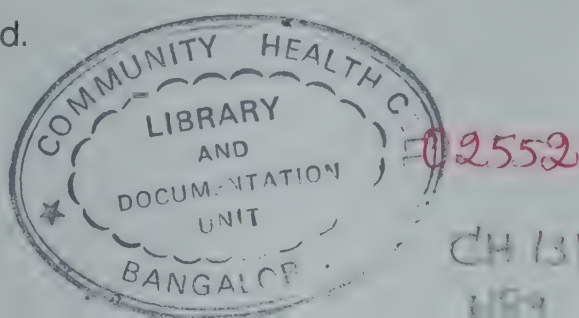
- Keep records of vaccines distributed and estimated utilization at the centres.

3.4 DISTRIBUTE VACCINES

Your major responsibility is to provide vaccines to the health centres in time.

You will receive the indents from the PHCs indicating the total quantities required by them. Before making supplies, you must check the following:

1. requirements of the PHC
2. utilization during the previous months
3. estimated balance in hand.



You must supply adequate quantities to meet the requirements of the PHCs. But you must also ensure that large stocks do not accumulate at the PHCs.

Estimates of vaccine requirements have been described earlier in the module.

Vaccine utilization will depend on the number of vaccinations performed and the number of sessions held. Add the total of all the doses of each vaccine given during the month and make an allowance for the administration rate. If the vaccine utilization is low, discuss the matter with the PHC doctor.

Check that the cold boxes and vaccine carriers are sufficient in number and in proper condition. Check that the ice packs are frozen and the number of vaccine carriers is sufficient.

If you are supplying the vaccine, make sure that you prepare enough ice packs prior to the date of vaccine supplies.

If the vaccines are being collected from your store, keep ice packs handy. These can be replaced with unfrozen ice packs brought from the PHCs which may not have enough freezing capacity.

3.5 MONITOR COLD CHAIN

You will need to monitor regularly your cold chain system if you expect it to function effectively and efficiently.

You would need to monitor:

- (a) supplies
- (b) temperature during transport
- (c) storage temperatures
- (d) potency tests.

(a) Supplies:

Regular and smooth flow of vaccines and their proper utilization will relieve many bottlenecks. It will avoid artificial shortages created by accumulation of large balance stocks at places where the programme is not functioning effectively. It will minimize the risks of cold chain failures as the vaccines are kept for short durations at the peripheral levels.

Arrange supplies according to demand and *utilization*. Estimate usage from performance reports.

Make a physical check of vaccine stocks during your supervisory visits.

Make sure that records are properly maintained.

(b) Temperature during transport

Vaccine cold chain monitors have been introduced in the National Immunization Programme for monitoring the temperature. A model cold chain monitor with instruction is given at annexure-4

(c) Storage temperatures

The temperature of the refrigerators used for the storage of vaccines must be recorded twice daily. These records should be checked during supervisory visits. A break in the cold chain is indicated if the temperature rises above +8 degree C. or falls below +2 degree C.

You may use the checklist for the proper storage of vaccines in the refrigerator.

Checklist:

A. Is the refrigerator

1. Level?
2. Away from sunlight?
3. Locked?
4. Defrosted periodically?
5. Plugged to socket permanently?
6. Not used for food or drink?

B. Are the vaccines

1. Stacked neatly?
2. Rotated?
3. Not kept in the door?
4. Not frozen? (except polio and measles)
5. Not date expired?

(c) Potency tests

The ultimate test of the quality of the cold chain system will be its effectiveness in keeping vaccines potent till the point of use.

Testing facilities are available at the Central Research Institute, Kasauli (H.P.), National Institute of Communicable Diseases, Delhi and Enterovirus Research Centre, Bombay
New testing centres are shown in the annexure.

OPV has been taken as "indicator" of the quality of the cold chain as this vaccine is more heat labile than other vaccines, and it is easier to test. The test takes only 7 days to complete and does not require scarce laboratory animals.

Opened vials can also be sent for testing and the vials should be lifted from all levels — from the village to district stores.

The samples should be sent packed in ice otherwise there will be a drop in the virus titre during transportation.

You must lift OPV vials during your field visits and send them to your State officer. The samples can be periodically lifted - say once or twice a month. The vaccine samples should be kept in freezer before these can be sent to the state Officer. You must monitor the storage very carefully to make sure that there is no fall in potency during storage at your store.

While sending samples for testing you must indicate clearly the place from where the sample(s) were lifted, date when it was lifted and batch number and expiry date of the vial.

Exercise H

Instructions: Read the following situation and answer the questions below. Write your answers in the space provided after each question.

Situation: You visit one of your health centres and discover that it has more vaccine than can possibly be used in the next two months. If this vaccine is stored in the health centre beyond one month, some of it will expire. The health centre's supply period is one month.

Questions: 1. What would be the likely causes of this surplus?

2. What actions would you take to protect the vaccine and ensure its utilization?

3. What actions can be taken to prevent the problem from occurring again?

Exercise I

Instructions: Read the following situation and answer the question below. Write **your** answer in the space provided after the question.

Situation: At present you keep supplies for twelve health centres in the district. The storage capacity in your store is sufficient for only three months' supply of vaccine for these health centres. Six other health centres in your region have recently received refrigerators. The services will be intensified under National Immunization Programme. As a result the vaccine requirements in the district are expected to double. The district store will not be able to increase its storage capacity in time for the expanded activities, and as a result there will not be adequate space to store all the vaccines.

Question: What would you do to deal with this situation.?

Exercise J

Instructions: Read the following situation and answer the question below. Write your answers in the space provided after each question.

Situation : You are responsible for the cold chain at a district store. You have two refrigerators, one ILR and one freezer. You also have several cold boxes and vaccine carriers. At any given time, you have at least 25,000 doses of any one kind of vaccine in your store.

You are asked to make emergency plans for what you will do with your vaccine in the event of an electricity failure.

- Questions:*
1. When should you make emergency plans and what should these plans include?
 2. What would your emergency plan be if the electricity will be restored within 2 hours?
 3. What would your emergency plan be if the electricity will not be restored within 2 hours?

When you have completed this exercise, consult a course manager to discuss your answers to Exercises H, I, J.

NATIONAL IMMUNIZATION PROGRAMME **VACCINE MONITORING SHEET**

Session Site _____ SC _____
 PHC _____ District _____
 Date of session _____ Dt Vaccines obtained _____
 Institution (Storage point) from where obtained _____

Sl. No.	Particulars	DPT	OPV	VACCINES MEASLES	BCG	TT			DT
1	No. of vials obtained								
2	Batch No. & expiry date of vial (s) opened for the session								
3	Benefeciaries					10 yr.	16 yr.	PW	
	Tally-mark each beneficiary under appropriate column	Less than 1 year							
		Above 1 year							
	No. of unopened vials returned								

USED VIALS RETURNED TO SUPERVISOR

Session Site _____ Date of Session _____

Vaccine	Batch No.	Exp. Date	No. of Vials
DPT			
BCG			
MEASLES			
TT			
DT			

Signature _____
Date _____

Supervisor will keep these vials in proper cold chain for at least 7 days before destroying.

[illegible]

Note : All live births should be taken to infants register and indicate page No. and serial No.

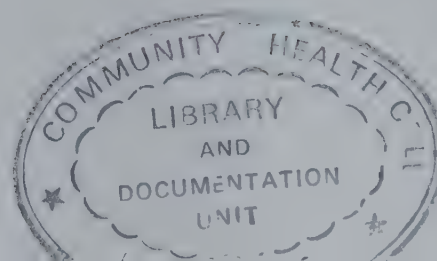
* Result is to be recorded as : L. B = Live Birth
S. B = Still Birth
A = Abortion

YEAR

[illegible]

Additional facilities for O P V TESTING

- School of Tropical Medicine, Calcutta,
- King Institute Guindy, Madras
- National Institute of Virology, Pune
- B.H.U. Medical college, Varanasi
- Institute of Preventive Medicine, Hyderabad.
- B.J. Medical College, Ahmedabad and
- S.M.S Medical College, Jaipur



Notes

Notes

Notes

